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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,374	11/16/2001	Michael A. Apicella	875.009US2	2605

21186 7590 05/29/2003

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/991,374

Applicant(s)

APICELLA ET AL.

Examin r

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**DETAILED ACTION**

Claims 1-12 are presented for examination.

***Information Disclosure Statement***

The information disclosure statement (IDS) filed February 12, 2002, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

It is noted that the IDS cover sheet states that copies were not provided because "these references were previously cited by or submitted to the U.S. Patent Office in connection with Applicants' prior U.S. application, Serial No. 09/991,374, filed on November 16, 2001, which is relied upon or an earlier filing date under 35 U.S.C. § 120." However, this case *is* Serial No. 09/991,374. Thus, no copies of the references were filed in the parent application, because 09/991,374 is not the parent to this application. Rather, this case *is* Serial No. 09/991,374, and no copies of the cited documents were filed.

The IDS has been placed in the application file, but the information referred to therein has not been considered, except to the extent that any references are referred to herein.

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***Claim Objections***

Claims 1, 11 and 12 are objected to because of the following informalities:

the term -- oligosaccharide -- has been misspelled as "ologosaccharide."

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 12 recites the process of claim 10, wherein the polysaccharide is incorporated into a vaccine. This makes no sense because claim 10 is directed to a method of "producing a complex carbohydrate." The production of a complex carbohydrate does not require, or even encompass, a step of incorporating the carbohydrate into a vaccine. One does not produce a carbohydrate by incorporating it into a vaccine.

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Because claim 12 recites a step which does not fall within those encompassed by the preamble of the previous claim, claim 12 is confusing when taken in context, and therefore indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one ~~year prior to the date of application for patent in the United States.~~

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Abu Kwaik et al (Molecular Microbiology 5(10):2475-2480 (1991)).

Abu Kwaik et al describe the production of recombinant strains of *E. coli* JM 109 which contain the genes encoding the enzymes responsible for formation of an oligosaccharide moiety characteristic of *Haemophilus influenza* type b lipooligosaccharide. See, e.g. abstract. Note specifically that applicant's own specification (page 4, lines 25 and 26) makes it clear that JM 109 inherently produces the lipopolysaccharide core recited as limitation (a) of claim 1. Note further that the presence in the bacterium of an acceptor-

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adding enzyme, recited in limitation (b) of claim 1, is considered to be inherently met by Abu Kwaik because the reference uses the same strain as recited in the claims, *E. coli* JM 109, which inherently contains an *rfe* (*wecA*) gene. Still further, limitation (c) is met by the reference since the genes encoding the enzymes from *H. influenza* were inserted into the bacterium. Note further the production of lipopolysaccharides from the transformed bacteria, and the analysis thereof by SDS-PAGE. See Fig. 2, on page 2476.

On the current record, it appears that the strains recited in the claims and disclosed in the specification, including the examples, are exactly the strains described by Abu Kwaik. Compare Fig. 1, on page 2476 of Abu Kwaik, to Fig. 1 of the instant application. Based on the evidence of record, the same bacterial strain, *E. coli* JM 109, has been modified using the same plasmids, pGEMLOS-1, -4, -5 and 7. Thus, while Abu Kwaik does not explicitly disclose all elements recited in the claims, the transformed bacteria in the reference inherently possess all of the properties required by the claims. A holding of anticipation is clearly required.

Claims 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Abu Kwaik et al (Molecular Microbiology

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5(10):2475-2480 (1991)), taken in light of Westphal et al  
(*Methods in Carbohydrate Chemistry*, Whistler et al, eds., vol.  
5, pp. 83-91, Academic Press, New York (1964)).

As discussed above, Abu Kwaik et al describe the production of recombinant strains of *E. coli* JM 109 which contain the genes encoding the enzymes responsible for formation of an oligosaccharide moiety characteristic of *Haemophilus influenza* type b lipooligosaccharide. The reference also describes that the method of Westphal was used to prepare the lipopolysaccharides for SDS-PAGE analysis. See page 2479, first column on left. Westphal discloses the preparation of lipopolysaccharides in water solutions. See page 86 ("[t]he final sediment is taken up in a minimum amount of water"; see also page 88 ("[a]fter dialysis for 2 days against deionized water to remove sodium chloride, the solution is freeze-dried" \* \* "[a]fter centrifugation, the sediment is dissolved in water"). Therefore, as evidenced by Westphal, Abu Kwaik inherently describes the preparation of lipopolysaccharides in water solutions, which can be used as vaccines. Abu Kwaik therefore describes the incorporation of the lipopolysaccharides into vaccines, as recited in claim 12.

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Claims 1-3, 5 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Brade et al (Infection and Immunity 55(2):482-486 (1987)).

Brade describes the transformation of *Salmonella minnesota* with plasmids containing a 6.5 kb insert assumed to encode a glycosyltransferase. See abstract. The described strains clearly meet limitation (a) of claim 1, requiring a core region with a terminal heptose, since the reference discloses the use of the same host species of microorganism, *Salmonella minnesota*, as recited in the claims. Moreover, the transformation and resulting production of modified lipopolysaccharides demonstrates the presence of the enzymes recited in limitations (b) and (c) of claim 1. The lipopolysaccharides produced by the transformed strains, modified with the chlamydial epitope, were prepared in water solutions suitable for use as vaccines (see page 483, section entitled "Bacteria and bacterial LPS"), and were hydrolyzed by acid for study (see, e.g., Fig. 2), thereby meeting the limitations required in claims 10-12. A holding of anticipation over the cited claims is therefore clearly required.

No claims are allowed.

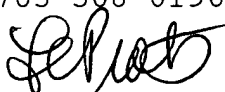


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
May 19, 2003